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Purpose/Objective: Radiotherapy (RT) is a valuable treatment modality for potential cure and palliation, for patients with lung cancer. Reports have established that RT is greatly underutilised in Australia, presumably due to geographic and economic factors. In a public private partnership (PPP) between Radiation Oncology Queensland (ROQ) and the Queensland State Government, a no patient cost (NPC) RT centre was established in 2013. Prior to the establishment of ROQ at the Gold Coast University Hospital, patients were required to travel 70km for an NPC service. The Aim of this study was to investigate the impact of a PPP RT centre, with on-site radiation oncologists, on RT utilisation rates and delays to commencement of RT, compared to immediate historical figures of when patients were required to travel for no cost RT.

Materials and Methods: Queensland Oncology Online database was used to identify patients with a new diagnosis of or new problem relating to Small Cell or Non Small Cell Lung Cancer. All such patients discussed at the Gold Coast University Hospital Lung Multi-disciplinary Meeting between the dates of 17th June 2013 and 17th Jun 2014, were included for analysis. The first RT simulation at ROQ was performed on 17 December 2013: all patient problems discussed 6 months prior to this were classified as Pre ROQ, and those discussed from 17 December onwards as Post ROQ. Electronic records were accessed to determine which patients had received RT, the indication, date of referral and the date of first RT fraction. Primary end points were indication-based utilisation rates, as well as time from referral to commencement of RT. Evidence-based indications for RT in lung cancer include: curative intent, palliation of bone and brain metastases and palliation of symptomatic thoracic disease.

Results: A total of 158 patients (Pre ROQ 77 v Post ROQ 81) were identified for the study. There were no significant demographic differences between the Pre ROQ and Post ROQ groups. A statistically significant increase in indication-based utilisation was noted (83% v 98% p = 0.03). Pre ROQ, the most common under-referred indications were palliation of symptomatic thoracic disease and bone metastasis. A statistically significant reduction in mean time to commencement of RT was also noted following the introduction of ROQ (23 days v 27 days p = 0.03).

Conclusions: The introduction of the first PPP RT Centre in Australia's fifth largest city has lead to increased indication-based RT utilisation rates and shorter waiting times for patients with lung cancer.

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Clinical trial real time review in post-prostatectomy radiotherapy: is there room to risk adapt?

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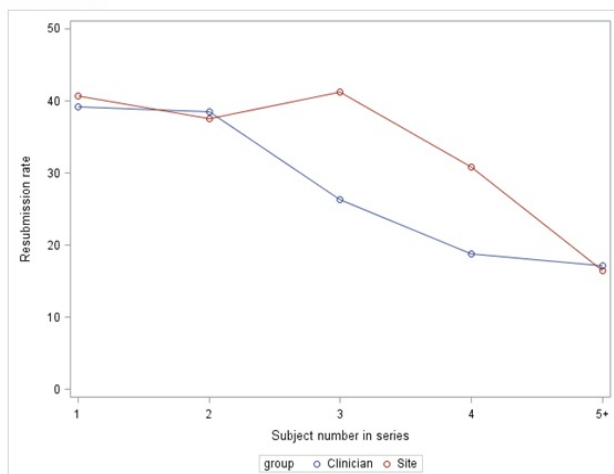
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Purpose/Objective: Radiotherapy (RT) Quality Assurance (QA) is an essential component of a clinical trial to ensure standardised treatment. It is unclear if there is scope to risk adapt QA intensity. We explore the site- and clinician-level factors which are associated with Real Time Review (RTR) resubmission to help tailor future QA protocols.

Materials and Methods: RAVES is a randomised trial comparing adjuvant with early salvage RT in men with positive surgical margins or pT3 disease following radical prostatectomy. QA in RAVES requires each clinician and site to submit a credentialing dummy-run (DR) and for each patient RT plan to undergo external RTR prior to commencing treatment. Prospectively defined major violations from trial protocol required remedy and resubmission prior to starting treatment. Reports from DR and RTRs were collated and violations were categorised into target volume contouring, critical structure contouring, dosimetric or other. Site and clinician factors associated with RTR resubmission were examined using hierarchical modelling. These included: incidence of DR resubmission, number of cases per clinician and site, time between initial credentialing and RTR, and RT technique (3DCRT v IMRT).

Results: Data were collected from 171 consecutive patients, treated by 46 clinicians at 32 hospitals between June 2009 and October 2014. There were 47 RTR resubmissions (27% of all cases) and 65 major violations in total. The majority of resubmissions were due to contouring (39/65) or dosimetric violations (22/65). The majority of contouring violations (90%) related to target volumes (CTV and PTV). Significant decreases in RTR resubmissions were seen at both clinician and site level for each additional patient accrued. For each additional case submitted, the relative risk of resubmission decreased by 25% at the clinician level (Hazard Ratio [HR] 0.75, p=0.02) and by 28% by site (HR 0.72, p=0.01). The rate of resubmission dropped from 40% for first patient submitted from each clinician or site to 20% after ≥5 patients. Use of IMRT was associated with lower rate of resubmission compared to 3DCRT (HR 0.38, p=0.05). At site level, rate of resubmission due to dosimetric violation after first five submissions was only 2% (2/103). For a clinician, a DR resubmission was correlated with a non-statistically significant 59% increase in the relative risk of a subsequent RTR resubmission (Adjusted HR 1.59, p>0.1). The lowest risk for resubmission were clinicians that did not need DR or first RTR resubmission (17%) compared to high risk group that needed both resubmitted (44%).

FIGURE 1. Rate of resubmissions in percent by subject number in series, at the clinician and site level.



Conclusions: Several low and high risk factors were identified which may assist with tailoring future clinical trial QA. RTR are essential due to a baseline level of resubmission, which is independent of clinician or site factors. There is a scope for modifying RTR QA to include only contouring RTR submissions at high volume sites. The lower rate of resubmission for cases using IMRT may be a surrogate for advanced technology implementation at a particular site.

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FMECA application to IORT procedure as a quality method to prevent and reduce patient's risk

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Purpose/Objective: Our Center acquired a mobile electron linear accelerator for intraoperative radiation therapy (IORT) and the clinical activity started at the end of June 2012. The risk assessment performed before the start of clinical activity was integrated with a predictive matrix risk analysis (FMECA). Two years later an analysis of all the relevant criticalities was performed in order to improve quality. The aim of this study is to present the results of the method elaborated by our Working Group and the application of FMECA prospective approach to IORT procedure.

Materials and Methods: A multidisciplinary Working Group was created, including different professional profiles. Each member of the Working Group was asked to identify a priori the criticalities he/she could meet in the process steps concerning his/her specific activity. In this way a list of all potential failure modes (FM) occurring in each process step was drafted.

The risk analysis was completed by asking the members of the team to evaluate the Risk priority number (RPN) of each FM.

Two years after the beginning of IORT clinical activity, the risk analysis was repeated by the Working Group, in order to assess the improvement achieved.

Results: The IORT process was subdivided in 43 steps and 39 criticalities were identified by the Working Group. They represented the issues prospectively investigated according to the FMECA method. An Excel worksheet was created, inserting in rows: process step, professional figures involved, failure mode, potential effects of failure, potential causes of failure, preliminary RPN and corrective actions. In the re-analysis of the process - two years later - the final RPN was elaborated and the risk reduction (RR) (preliminary RPN - final RPN) was also calculated, in order to assess the weight of the corrective measures. The highest score was attributed to the misalignment of the internal shield, used to protect the underlying normal tissues, with a risk reduction equal to 20 (25%) after corrective actions. The next critical scores were related to the inaccurate placement of the applicator in the tumour bed (RR: 28; 43,8%) and the wrong definition of the CTV (RR: 48; 75%). Another relevant failure mode was the inadequate placement of the dosimeter (gafchromic film) on top of the internal shield. In most cases this risk was prevented following the 'in vivo dosimetry' Procedure, elaborated by our Medical Physicist (RR: 28; 46.7%).

Conclusions: The FMECA technique has provided a prospective systematic method for discovering potential failures in IORT procedure; evaluating not only the frequency of FM but also their severity and detectability, it has given a more complete assessment of the risks. It contributes therefore to optimize patient safety right from the start of our clinical activity and to improve risk management culture among all the professionals involved in the Working Group.

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The definition of an auditable and complete dataset for lung cancer patients - the RTTis role

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Purpose/Objective: The North West area has one of the largest number of lung cancer patients in the U.K. Data collected for these patients relating to treatment outcome and graded toxicities does not currently allow us to accurately assess these data. In conjunction with a radiation oncology professor and a research fellow, an RTT has been heavily involved in the definition, production and design of a defined, auditable dataset for lung cancer patients.

Materials and Methods: Our institution is attempting to implement a data warehouse product into its information technology structure in order to make information more accessible to staff conducting audit and research. In the baseline assessments made during the set up of the data warehouse, the chair of radiation oncology appraised the data collected for patients and a decision was made to improve the quantity, and more importantly, the quality of the data recorded. On a disease site specific basis, and beginning with lung (a large patient group with poor outcomes), a work stream was set up in order to define an